

GERALD SINGLETON (208783)  
gsingleton@singletoschreiber.com  
 MIKAL C. WATTS (PRO HAC FORTHCOMING)  
mcwatts@wattsguerra.com  
 ALICIA D. O'NEILL (PRO HAC FORTHCOMING)  
aoneill@wattsguerra.com  
 ATTORNEY'S FOR PLAINTIFFS

**UNITED STATES DISTRICT COURT  
 CENTRAL DISTRICT OF CALIFORNIA**

**JASMINE RIOS, INDIVIDUALLY AND AS  
 GUARDIAN AD LITEM OF A.L., MINOR**

**Plaintiff(s),**

**v.**

**CVS PHARMACY INC., WALGREENS  
 BOOTS ALLIANCE, and WALMART INC.,**

**Defendants.**

**Civil Action No.:**

**COMPLAINT & JURY DEMAND**

**DEMAND FOR JURY TRIAL**

**PLAINTIFF'S ORIGINAL COMPLAINT AND JURY DEMAND**

Plaintiff Jasmine Rios individually and as representative of A.L., a minor, pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendants CVS Pharmacy Inc., Walgreens Boots Alliance, and Walmart Inc. (hereinafter, "Defendants") and in support, state the following:

1. This is an action brought on behalf of Plaintiffs, Jasmine Rios (hereinafter, "Plaintiff Mother"), the natural and general guardian and mother of A.L. (hereinafter, "Plaintiff Child"), a minor, arising out of the failure of Defendants to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter "APAP"). As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendants entirely failed their duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and

1 associated damages.

2 **STATEMENT OF PARTIES**

3 3. At all material times Plaintiffs have been citizens and residents of San Bernadino  
4 County, California.

5 4. CVS Pharmacy, Inc. is incorporated in Delaware with its principal place of  
6 business in Woonsocket, Rhode Island.

7 5. Walgreens Boots Alliance is incorporated in Deerfield, Illinois with its principal  
8 place of business in Deerfield, Illinois.

9 6. Walmart is incorporated in Delaware, with its principal place of business in  
10 Bentonville, Arkansas.

11 7. CVS Pharmacy, Inc. is involved in the research, development, testing,  
12 manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-  
13 the-counter store brand, Acetaminophen (hereinafter, the “APAP Products”).

14 8. Walgreens Boots Alliance is involved in the research, development, testing,  
15 manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-  
16 the-counter store brand, Acetaminophen (hereinafter, the “APAP Products”).

17 9. Walmart Inc., is involved in the research, development, testing, manufacture,  
18 labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter  
19 store brand, Acetaminophen (hereinafter, the “APAP Products”).

20 10. CVS Pharmacy, Inc. is individually, and jointly and severally liable to Plaintiffs  
21 for damages they suffered, arising from Each Defendant’s design, manufacture, marketing,  
22 labeling, distribution, sale, and placement of the defective APAP Products into the market,  
23 effectuated directly and indirectly through its agents, servants, employees, and/or owners, all  
24 acting within the course and scope of its agencies, services, employments, and/or ownership.

25 11. Walgreens Boots Alliance is individually, and jointly and severally liable to  
26 Plaintiffs for damages they suffered, arising from Each Defendant’s design, manufacture,  
27 marketing, labeling, distribution, sale, and placement of the defective APAP Products into the  
28 market, effectuated directly and indirectly through its agents, servants, employees, and/or

1 owners, all acting within the course and scope of its agencies, services, employments, and/or  
2 ownership.

3 12. Walmart Inc., is individually, and jointly and severally liable to Plaintiffs for  
4 damages they suffered, arising from Defendant' design, manufacture, marketing, labeling,  
5 distribution, sale, and placement of the defective APAP Products into the market, effectuated  
6 directly and indirectly through its agents, servants, employees, and/or owners, all acting within  
7 the course and scope of its agencies, services, employments, and/or ownership.

8 13. CVS Pharmacy, Inc. is vicariously liable for the acts and/or omissions of its  
9 employees and/or agents, who were at all material times acting on behalf of CVS Pharmacy,  
10 Inc. and within the scope of its employment or agency.

11 14. Walgreens Boots Alliance is vicariously liable for the acts and/or omissions of its  
12 employees and/or agents, who were at all material times acting on behalf of Walgreens Boots  
13 Alliance and within the scope of its employment or agency.

14 15. Walmart Inc., is vicariously liable for the acts and/or omissions of its employees  
15 and/or agents, who were at all material times acting on behalf of Walmart Inc., and within the  
16 scope of its employment or agency.

17 **JURISDICTION and VENUE**

18 16. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on  
19 complete diversity of citizenship between Plaintiffs and Defendants. *See supra* ¶¶ 3–4.

20 17. The amount in controversy exceeds \$75,000.

21 18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or  
22 omissions giving rise to Plaintiffs' claims occurred in this judicial district.

23 19. Defendants have conducted and continue to conduct substantial business in the  
24 State of California and in this District, distribute the APAP Products in this District, receive  
25 substantial compensation and profits from sales of the APAP Products in this District, and have  
26 made material omissions and misrepresentations and breaches of warranties in this District and  
27 caused injuries in this District to Plaintiffs, among others, so as to subject Defendants to in  
28 personam jurisdiction in this District. It was foreseeable at all times that Defendants could be

1 haled into court in the State of California for its conduct that caused injuries to citizens of  
 2 California, like Plaintiffs in this action. An exercise of in personam jurisdiction by this Court  
 3 over Defendants comports fully with due process and does not offend traditional notions of fair  
 4 play and substantial justice.

5 20. Defendants are registered to transact business in California.

6 **FACTS COMMON TO ALL COUNTS**

7 **APAP Is Marketed as the Safe Pain Reliever for Pregnant Women, but APAP Can Cause**

8 **ASD/ADHD in Children**

9 21. APAP is widely used by pregnant women to relieve pain or discomfort during  
 10 the term of their pregnancy.

11 22. APAP was initially discovered in the late 1800's.

12 23. APAP was introduced to the US market in 1955 as the first aspirin-free pain  
 13 reliever. APAP was originally marketed and sold as a product to reduce fever in children,  
 14 packaged like a red fire truck with the slogan, "for little hotheads."

15 24. Billions of units of APAP are sold annually in North America alone.

16 25. APAP has long been marketed as the safest, and the *only* appropriate, over-the-  
 17 counter pain relief drug on the market for pregnant women.

18 26. Forty to 65% of pregnant women in the United States use APAP during  
 19 pregnancy.

20 27. Based upon information and belief, a majority of women who use APAP during  
 21 pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and  
 22 discomfort.

23 28. These pregnant women electively choose to take APAP because Defendants have  
 24 marketed APAP as a safe pain reliever for pregnant women.

25 29. However, scientific and epidemiological research shows that prenatal exposure  
 26 to APAP alters fetal development significantly increasing the risks of neurodevelopmental  
 27 disorders, including but not limited to, autism spectrum disorder ("ASD") and attention-  
 28 deficit/hyperactivity disorder ("ADHD").

1           30.     Undisturbed development of the human brain in utero is vital to the health and  
2     wellness of a child's development. The human brain is vulnerable and extremely sensitive in  
3     utero. During this sensitive time-period in utero, certain chemicals have been found to cause  
4     permanent brain injury at low exposure levels.

5           31.     Once ingested by the mother, APAP is known to readily cross the placenta and  
6     blood-brain barrier.

7           32.     ASD is a serious neurological and developmental disorder that affects how  
8     people interact with others, communicate, learn, and behave.

9           33.     There are three functional levels of ASD, with Level 1 requiring support with  
10    activities of daily living, Level 2 requiring substantial support with activities of daily living, and  
11    Level 3 requiring very substantial support with activities of daily living.

12          34.     Treatments for ASD include behavioral management therapy, cognitive behavior  
13    therapy, joint attention therapies, medications, occupational therapy, physical therapy, social  
14    skill training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no  
15    cure.

16          35.     ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,  
17    hyperactivity, and impulsiveness.

18          36.     ADHD begins in childhood and persists through adulthood. ADHD contributes  
19    to low self-esteem, troubled relationships, and difficulty with school, work, and familial  
20    relationships.

21          37.     Treatments for ADHD, include, but are not limited to, chronic medication usage  
22    and various therapies. Treatment for ADHD lasts a lifetime, as there is no cure.

23          38.     In or around 2018, the Center for Disease Control and Prevention ("CDC")  
24    found that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

25          39.     This represents an increase from a prior CDC finding that 1 in 68 U.S. children  
26    born in 2002 have ASD, which already represented a more than a 100% increase compared with  
27    children born a decade prior.

1           40.     As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly  
2     325,000 children per year.

3           41.     Parental awareness and changes in diagnoses do not fully account for the rapid  
4     rise in these diagnoses.

5           42.     Rather, neurotoxic exposures, such as prenatal APAP exposure, partly explain a  
6     trending increase in diagnoses.

7           43.     For decades, beginning in 1987, the scientific community has published studies  
8     showing that prenatal ingestion of APAP can cause ASD and ADHD.

9           44.     A 2019 meta-analysis of studies from 1987 to 2016, with relative risks ranging  
10    from 1.16 to 1.34, found statistically significant nineteen percent (19%) increased risk of ASD  
11    in children whose mothers took APAP during pregnancy.

12          45.     Since 2013, there have been six European birth cohort studies, examining over  
13    70,000 mother-child pairs, showing the association between prenatal use of APAP and ASD and  
14    ADHD, confirming the results of studies dating back to 1987.

15          46.     The overall body of scientific evidence has shown for decades that prenatal use  
16    of APAP can cause ASD and ADHD in the child.

17          47.     During all relevant times herein, Defendants was engaged in the business of  
18    manufacturing and selling the APAP Products in the United States, and the weight of the  
19    scientific evidence available showed prenatal exposure to APAP significantly increases the risk  
20    of neurodevelopmental disorders in children exposed to APAP prenatally, including but not  
21    limited to ASD and ADHD.

22          48.     At the time Plaintiff Mother was pregnant with Plaintiff Child the scientific  
23    evidence regarding the risks of in utero exposure of APAP was available to Defendants, and  
24    Defendants knew or should have known that prenatal use of APAP can cause ASD or ADHD.

25          49.     Moreover, despite scientific evidence that prenatal use of APAP can cause ASD  
26    or ADHD, Defendants continued and continue, to market APAP Products as safe pain relievers  
27    for pregnant women, making mothers believe they are choosing a safe drug for even minor  
28    aches, pains, and headaches.

**Plaintiff Mother Took APAP Products while Pregnant,  
and It Caused ASD in Plaintiff Child**

50. Plaintiff Mother used APAP Products while she was pregnant with Plaintiff Child.

51. During her pregnancy with Plaintiff Child, during every trimester, Plaintiff Mother took the APAP Products more than once a week for pain relief.

52. Plaintiff Mother believed it was safe for her to take APAP Products during her pregnancy.

53. Indeed, Plaintiff Mother was instructed by her health care provider(s) to not take ibuprofen or aspirin while pregnant but was informed she could take APAP freely without risk to Plaintiff Child.

54. There is no warning on the APAP Products' labels specifically addressing the risks of ASD if a mother ingests APAP while pregnant.

55. Had Plaintiff Mother known of the risk of ASD in her child from taking APAP while pregnant, she would not have taken the APAP Products.

56. Plaintiff Child was born on November 9, 2017.

57. Plaintiff Mother started to have concerns about Plaintiff Child's development before he began school. Specifically, at that time, Plaintiff Child exhibited developmental delays and limited communication skills.

58. Plaintiff Child did not learn to speak until he was four years old.

59. Plaintiff Child was diagnosed with autism on June 20, 2022.

60. Plaintiff Child exhibits stimming behaviors in the form of repetitive, unusual body movements and/or noises like swinging his arms back and forth.

61. Plaintiff Child also engages in behaviors of banging his head on the wall, not interacting with other children, covering his ears to avoid common loud noises, lining up toys, and having excessive tantrums.

62. Plaintiff Child requires an immense amount of assistance to complete the normal tasks of his daily life.

63. Plaintiff Child's ASD puts an incredible strain on Plaintiff Mother and their family.

64. Plaintiff's Mother fears for Plaintiff Child and experiences substantial stress and anxiety due to the challenges associated with Plaintiff Child's ASD.

### **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

65. Due to Defendants' acts of fraudulent concealment, Defendants are estopped from relying on any statutes of limitations or repose. Such acts include Defendants' intentional concealment from Plaintiff Mother and the general public that APAP is defective when there is prenatal exposure, while continuing to market the APAP Products with the adverse effects described in this Complaint.

66. Given Defendants' affirmative actions of concealment by failing to disclose information about the defects known to it but not the public—information over which Defendants had exclusive control—and because Plaintiff Mother could not reasonably have known that the APAP Products were defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

67. Plaintiffs, in any event, commenced this action within two years of discovering or having reason to discover their causes of action.

### **CLAIMS FOR RELIEF**

#### **COUNT I: STRICT LIABILITY – FAILURE TO WARN**

68. Plaintiffs restate, reallege, and incorporate by reference the allegations set forth in the rest of this Complaint as if fully set forth herein.

69. At the time of Plaintiffs' injuries, the APAP Products were defective and unreasonably dangerous to foreseeable consumers using the APAP Products in a foreseeable manner during pregnancy, including Plaintiff Mother, because they lacked an adequate warning.

70. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, and promoting the APAP Products, which were defective and unreasonably dangerous to consumers, including Plaintiff



1 Mother, because they did not contain adequate warnings or instructions concerning the  
2 dangerous characteristics of ingesting APAP during pregnancy. These actions were under the  
3 ultimate control and supervision of Defendants. At all relevant times, Defendants registered,  
4 researched, manufactured, distributed, marketed, labeled, promoted, and sold the APAP  
5 Products within this District and aimed the marketing at the ultimate consumer. Defendants  
6 was at all relevant times involved in the retail and promotion of the APAP Products marketed  
7 and sold in this District.

8 71. Defendants had a duty to warn of the risks associated with the use of the APAP  
9 products during pregnancy.

10 72. The APAP Products ingested by Plaintiff Mother during pregnancy were in the  
11 same or substantially similar condition as they were when they left possession of the  
12 Defendants.

13 73. Defendants expected and intended the APAP Products to reach users such as  
14 Plaintiff Mother in the condition in which the APAP Products were sold.

15 74. Plaintiff Mother did not materially alter the APAP Products prior to ingestion.

16 75. Plaintiff Mother ingested the APAP Products during pregnancy as indicated on  
17 the APAP Products' labels.

18 76. Plaintiff Mother was unaware of the defects and dangers of the APAP Products  
19 during pregnancy and was specifically unaware that prenatal exposure increases the risk of brain  
20 and behavioral development of children in utero.

21 77. The labels on the APAP Products to consumers lack any warning specific to  
22 pregnant women. The information that Defendants did provide or communicate to consumers  
23 failed to contain relevant warnings, hazards, and precautions that would have enabled  
24 consumers such as Plaintiff Mother to utilize the products safely and with adequate protection  
25 during pregnancy, or to decide to not use or ingest the APAP Products at all.

26 78. This alleged failure to warn is not limited to the information contained on the  
27 APAP Products' labeling. Defendants were able, in accord with federal law, to comply with  
28 relevant state law by disclosing the known risks associated with exposure to or use of APAP

1 during pregnancy through other non-labeling mediums, including, but not limited to, promotion,  
2 advertisements, public service announcements, and/or public information sources. But  
3 Defendants did not disclose these known risks through any medium.

4 79. At all relevant times, Defendants had a duty to properly test, develop, design,  
5 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the  
6 APAP Products; provide proper warnings for the APAP Products; and take such steps as  
7 necessary to ensure the APAP Products did not cause users and consumers, and their children,  
8 to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn  
9 Plaintiff Mother of dangers associated with exposure to or use of APAP during pregnancy.  
10 Defendants, as a manufacturer, seller, and/or distributor of pharmaceutical medication, is held to  
11 the knowledge of an expert in the field.

12 80. At the time of manufacture, Defendants could have provided the warnings or  
13 instructions regarding the full and complete risks of the APAP Products during pregnancy  
14 because Defendants knew or should have known of the unreasonable risks of ASD and ADHD  
15 associated with prenatal exposure to and/or the use of such products.

16 81. At all relevant times, Defendants failed and deliberately refused to investigate,  
17 study, test, or promote the safety of the APAP Products, or to minimize the dangers to  
18 consumers of the APAP Products and to those who would foreseeably use or be harmed by the  
19 APAP Products, including Plaintiffs.

20 82. Defendants failed to adequately warn consumers, like Plaintiff Mother, about the  
21 significant increased risk of neurodevelopmental disorders in children exposed to APAP  
22 prenatally, including but not limited to ASD and ADHD.

23 83. Defendants failed to adequately inform reasonably foreseeable consumers, like  
24 Plaintiff Mother, of the proper usage of the APAP Products.

25 84. Even though Defendants knew or should have known that APAP posed a grave  
26 risk of harm to Plaintiff Child, Defendants failed to exercise reasonable care to warn of the  
27 dangerous risks associated with use and prenatal exposure.

28 85. Plaintiff Mother was exposed to the APAP Products during pregnancy without

1 knowledge of their dangerous characteristics.

2 86. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the  
3 APAP Products while using them for their intended or reasonably foreseeable purposes during  
4 pregnancy, without knowledge of their dangerous characteristics.

5 87. Plaintiff Mother could not have reasonably discovered the defects and risks  
6 associated with the APAP Products prior to or at the time of Plaintiff consuming APAP during  
7 pregnancy. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of  
8 Defendants to know about and disclose serious health risks associated with using the APAP  
9 Products.

10 88. If Plaintiff Mother had been properly warned of the defects, dangers, and risks  
11 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest  
12 the APAP Products at all. Defendants' failure to properly warn of those defects, dangers, and  
13 risks associated with prenatal exposure to APAP was a substantial factor in causing Plaintiffs'  
14 injuries and damages.

15 89. Defendants are liable to Plaintiffs for injuries caused by Defendants' negligent or  
16 willful failure, as described above, to provide adequate warnings or other relevant information  
17 and data regarding the appropriate use of the APAP Products and the risks associated with the  
18 use of APAP.

19 90. As a direct and proximate result of Defendants placing defective APAP Products  
20 into the stream of commerce, and Plaintiff Mother's foreseeable use and ingestion of the APAP  
21 Products during pregnancy, Plaintiff Child was exposed to APAP prenatally, causing him to  
22 develop ASD.

23 91. As a direct and proximate result of Defendants placing defective APAP Products  
24 into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and  
25 suffering, emotional distress, lost wages and earning capacity, and diminished quality of life.  
26 Plaintiffs respectfully seek all damages to which they may be legally entitled.

27 **COUNT II: NEGLIGENCE**

28 92. Plaintiffs restate, reallege, and incorporate by reference each of the allegations

1 set forth in the rest of this Complaint as if fully set forth herein.

2 93. Although Defendants had a duty to use reasonable care in testing, developing,  
3 designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing  
4 written instructions and warnings for the APAP Products, Defendants failed to do so.

5 94. Defendants, directly or indirectly, caused the APAP Products to be sold,  
6 distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all  
7 relevant times, Defendants registered, researched, manufactured, distributed, marketed,  
8 promoted, and sold the APAP Products within this district and aimed at a consumer market  
9 within this district.

10 95. Defendants knew, or in the exercise of reasonable care should have known, that  
11 the APAP Products were defectively and unreasonably designed and/or manufactured, and/or  
12 marketed, and were unreasonably dangerous and likely to injure persons that were prenatally  
13 exposed to them. Defendants knew or should have known that Plaintiff Mother was unaware of  
14 the dangers and defects inherent in the APAP Products when she was ingesting them during her  
15 pregnancy with Plaintiff Child.

16 96. At all relevant times, Defendants had a duty to exercise reasonable care in the  
17 marketing, advertisement, promotion, and sale of the APAP Products. Defendants' duty of care  
18 owed to consumers and the general public included providing accurate, true, and correct  
19 information concerning the risks of using APAP during pregnancy and appropriate, complete,  
20 and accurate warnings concerning the potential adverse effects of APAP and, in particular, the  
21 significantly increased risk of causing neurodevelopmental disorders in children through  
22 prenatal exposure to APAP.

23 97. At all relevant times, Defendants knew or, in the exercise of reasonable care,  
24 should have known of the hazards and dangers of APAP ingestion while pregnant and,  
25 specifically, the significantly increased risk of causing neurodevelopmental disorders in  
26 children through prenatal exposure to APAP.

27 98. Defendants failed to provide any kind of warning to pregnant consumers, like  
28 Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders

1 in children through prenatal exposure to APAP.

2 99. Accordingly, at all relevant times, Defendants knew or, in the exercise of  
3 reasonable care, should have known that use of the APAP Products during pregnancy could  
4 cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the  
5 users of these products, including Plaintiffs.

6 100. As such, Defendants breached their duty of reasonable care and failed to exercise  
7 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,  
8 supply, promotion, advertisement, packaging, sale, and distribution of the APAP Products, in  
9 that Defendants manufactured and produced defective APAP Products, which carry the  
10 significantly increased risk of causing neurodevelopmental disorders in children through  
11 prenatal exposure to APAP; knew or had reason to know of the defects inherent in the APAP  
12 Products; knew or had reason to know that a user's or consumer's use of the APAP Products  
13 during pregnancy created a significant risk of harm and unreasonably dangerous side effects;  
14 and failed to prevent or adequately warn of these risks and injuries.

15 101. Defendants had a duty to disclose the truth about the risks associated with  
16 exposure to or use of APAP during pregnancy in its promotional efforts outside of the context  
17 of labeling. Defendants were negligent in its promotion of APAP outside of the labeling  
18 context by failing to disclose material risk information as part of its promotion and marketing of  
19 the APAP Products, including through the internet, television, and print advertisements.

20 102. Despite Defendants' ability and means to investigate, study, and test the APAP  
21 Products and to provide adequate warnings regarding use during pregnancy, Defendants failed  
22 to do so. Indeed, Defendants wrongfully concealed information and further made false and/or  
23 misleading statements concerning the safety and use of APAP.

24 103. Defendants' negligence included:

- 25 a. Manufacturing, producing, promoting, formulating, creating, developing,  
26 designing, selling, and/or distributing the APAP Products while negligently  
27 and/or intentionally concealing and failing to disclose the results of trials,  
28 tests, and studies of APAP and the significantly increased risk of causing

1 neurodevelopmental disorders in children through prenatal exposure to  
2 APAP, and, consequently, the risk of serious harm associated with human  
3 use of APAP during pregnancy; and

4 b. Failing to undertake sufficient studies and conduct necessary tests to  
5 determine whether or not the APAP Products were safe for its intended  
6 consumer use and unborn children; and

7 c. Failing to provide adequate instructions, guidelines, and safety precautions to  
8 those persons Defendants could reasonably foresee would use the APAP  
9 Products during pregnancy; and

10 d. Failing to disclose to Plaintiff Mother, users, consumers, and the general  
11 public that use of APAP during pregnancy presents severe risks of  
12 neurodevelopmental disorders in children exposed to APAP prenatally; and

13 e. Failing to warn Plaintiff Mother, users, consumers, and the general public  
14 that the APAP Products' risk of harm was unreasonable and that there were  
15 safer and effective alternative medications or treatments available to Plaintiff  
16 Mother and other users and/or consumers; and

17 f. Representing that the APAP Products were safe for their intended purposes  
18 for pregnant women when, in fact, Defendants knew or should have known  
19 the APAP Products were not safe for their intended purposes; and

20 g. Declining to make or propose any changes to the APAP Products' labeling or  
21 other promotional materials that would alert users, consumers, and the  
22 general public of the risks of APAP, including to pregnant women; and

23 h. Advertising, marketing, and recommending the use of the APAP Products  
24 during pregnancy, while concealing and failing to disclose or warn of the  
25 dangers known by Defendants to be caused by the use of or exposure to  
26 APAP; and

27 i. Continuing to disseminate information to its consumers and the general  
28 public, which indicates or implies that the APAP Products are not unsafe for

1 pregnant consumer use; and

2 j. Continuing the manufacture and sale of the APAP Products with the  
3 knowledge that the APAP Products were unreasonably unsafe and dangerous.

4 104. Defendants knew and/or should have known that it was foreseeable that children  
5 such as Plaintiff Child would suffer injuries as a result of Defendants' failure to exercise  
6 ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the APAP  
7 Products to pregnant consumers, like Plaintiff Mother.

8 105. Plaintiff Mother did not know the nature and extent of the injuries that could  
9 result in her child from the intended use of and/or exposure to APAP prenatally.

10 106. Defendants' negligence was a proximate cause of Plaintiffs' injuries, i.e., absent  
11 Defendants' negligence, Plaintiff Child would not have developed ASD. That negligence was a  
12 substantial factor in causing Plaintiffs' injuries and damages.

13 107. Defendants' conduct, as described above, was reckless. Defendants regularly  
14 risked exposing Plaintiff Mother to the APAP Products while pregnant with Plaintiff Child, with  
15 full knowledge of the dangers of the APAP Products and that it could cause ASD in Plaintiff  
16 Child. Defendants made conscious decisions not to redesign, re-label, warn, or inform the  
17 unsuspecting public, including Plaintiff Mother. Defendants' reckless conduct therefore  
18 warrants an award of punitive damages.

19 108. As a direct and proximate result of Defendants placing the defective APAP  
20 Products into the stream of commerce, Plaintiffs have suffered permanent injuries, significant  
21 pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality  
22 of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

23  
24 **COUNT III: BREACH OF EXPRESS WARRANTY**

25 109. Plaintiffs restate, reallege, and incorporate by reference each of the allegations  
26 set forth in the rest of this Complaint as if fully set forth herein.

27 110. At all material times, Defendants manufactured, marketed, sold, distributed, and  
28 otherwise placed into the stream of commerce the APAP Products. These actions were under

1 the ultimate control and supervision of Defendants.

2 111. In advertising, marketing, and promoting the APAP Products to consumers, like  
3 Plaintiff Mother, Defendants expressly warranted that the APAP Products were safe for use and  
4 reasonably fit for their intended purposes, including use by pregnant mothers. In advertising,  
5 marketing, and otherwise promoting the APAP Products, Defendants intended for pregnant  
6 consumers to rely upon its representations regarding safety and fitness, in an effort to induce  
7 them to purchase and consume the APAP Products during pregnancy to relieve pain.

8 112. Defendants expressly warranted to Plaintiff Mother and pregnant consumers that  
9 the APAP Products were safe for ingestion during pregnancy.

10 113. Defendants had a duty to exercise reasonable care in the research, development,  
11 design, testing, packaging, manufacture, inspection, labeling, distributing, marketing,  
12 promotion, sale, and release of the APAP Products, including a duty to:

- 13 a. ensure that the APAP Products during pregnancy did not cause users and  
14 their unborn children unreasonably dangerous side effects; and
- 15 b. warn of dangerous and potentially incurable side effects; and
- 16 c. disclose adverse material facts, such as the true risks associated with the use  
17 of and exposure to APAP during pregnancy, when making representations to  
18 users, consumers, and the general public, including Plaintiff Mother.

19 114. Defendants had the ability to properly disclose the risks associated with APAP  
20 usage during pregnancy through multiple channels, not just labeling.

21 115. At all relevant times, Defendants expressly represented and warranted to the  
22 purchasers of the APAP Products, by and through statements made by Defendants in labels,  
23 publications, brochures, and other written materials intended for consumers and the general  
24 public, that the APAP Products were safe to human health and the environment, effective, fit,  
25 and proper for their intended use during pregnancy. Defendants advertised, labeled, marketed,  
26 and promoted the APAP Products, representing the quality to consumers and the public in such  
27 a way as to induce their purchases or use during pregnancy, thereby making an express warranty  
28 that the APAP Products would conform to the representations.



1           116. The representations about the APAP Products, as set forth herein, contained, or  
2 constituted affirmations of fact or promises made by the seller to the buyer, which related to the  
3 goods and became part of the basis of the bargain, creating an express warranty that the goods  
4 would conform to the representations.

5           117. Defendants breached express representations and warranties made to Plaintiff  
6 Mother, with respect to the APAP Products, including the following:

- 7           a. Defendants represented through their labeling, advertising, and marketing  
8 materials that the APAP Products were safe for use during pregnancy, and  
9 intentionally withheld and concealed information about the risks of serious  
10 injury associated with use of APAP and by expressly limiting the risks  
11 associated with use during pregnancy within its warnings and labels; and  
12           b. Defendants represented that the APAP Products were safe for use and  
13 intentionally concealed information that demonstrated that APAP carries the  
14 significantly increased risk of causing neurodevelopmental disorders in  
15 children through prenatal exposure to APAP, and that the APAP Products,  
16 therefore, were not safer than alternatives available on the market.

17           118. Plaintiff Mother detrimentally relied on the express warranties and  
18 representations of Defendants concerning the safety and/or risk profile of APAP during  
19 pregnancy in deciding to purchase the APAP Products. Plaintiff Mother reasonably relied upon  
20 Defendants to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff  
21 Mother would not have purchased or used the APAP Products during pregnancy had  
22 Defendants properly disclosed the risks associated with the APAP Products, either through  
23 advertising, labeling, or any other form of disclosure. Defendants' breach of the express  
24 warranties and representations concerning the safety and/or risk profile of APAP during  
25 pregnancy was a substantial factor in causing Plaintiffs' injuries and damages.

26           119. Plaintiff Mother had no knowledge of the falsity or incompleteness of  
27 Defendants' statements and representations concerning the APAP Products and could not have  
28 taken reasonable steps to notify Defendants of those matters or to seek repair or other remedies.

1           120. Plaintiff Mother used and/or was exposed to APAP during pregnancy as  
2 researched, developed, designed, tested, manufactured, inspected, labeled, distributed,  
3 packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by  
4 Defendants.

5           121. Had the warnings, labels, advertisements, or promotional material for the APAP  
6 Products accurately and adequately set forth the true risks associated with the use of such  
7 Products during pregnancy, including Plaintiffs' injuries, rather than expressly excluding such  
8 information, and warranting that the APAP Products were safe for their intended use, Plaintiffs  
9 could have avoided the injuries complained of herein.

10           122. As a direct and proximate result of Defendants' breach of express warranty,  
11 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,  
12 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all  
13 damages to which they may be legally entitled.

14                           **COUNT IV: BREACH OF IMPLIED WARRANTY**

15           123. Plaintiffs restate, reallege, and incorporate by reference each of the allegations  
16 set forth in the rest of this Complaint as if fully set forth herein.

17           124. At all material times, Defendants manufactured, marketed, sold, distributed, and  
18 otherwise placed the APAP Products into the stream of commerce.

19           125. At all material times, Defendants intended for the APAP Products to be  
20 consumed and ingested by pregnant women, like Plaintiff Mother; and Defendants impliedly  
21 warranted that the APAP Products and their component parts were of merchantable quality,  
22 safe, fit for such use, and adequately tested.

23           126. Defendants was aware that consumers, including Plaintiff Mother, would  
24 consume and ingest the APAP Products as directed by the Products' labels and promotional  
25 materials. Therefore, Plaintiff Mother was a foreseeable user of the APAP Products.

26           127. But Defendants failed to disclose that APAP has dangerous propensities when  
27 used as intended during pregnancy and that use of the APAP Products carries an increased risk  
28 of developing severe injuries, including Plaintiff Child's injuries.

128. The APAP Products were expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which they were manufactured and sold by Defendants.

129. Plaintiff Mother was an intended beneficiary of the implied warranties made by Defendants to purchasers of the APAP Products, including Plaintiff Mother.

130. In reliance upon Defendants' implied warranties, Plaintiff Mother purchased and used the APAP Products as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants. The failure of the APAP Products to be of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a substantial factor in causing Plaintiffs' injuries and damages.

131. Defendants breached their implied warranties to Plaintiffs in that the APAP Products were not of merchantable quality, nor were they safe or fit for their intended use or adequately tested.

132. The harm caused by the APAP Products far outweighed their benefit, rendering the APAP Products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

133. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

**COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS**

134. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

135. Plaintiff Mother purchased and used the APAP Products for primarily personal use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

136. Had Defendants not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the APAP Products, and

1 Plaintiffs would not have incurred related injury medical costs.

2 137. Defendants engaged in wrongful conduct and unlawful while at the same time  
3 obtaining under false pretenses moneys from Plaintiff for the APAP Products. Those moneys  
4 would not have been paid had Defendants not engaged in unfair and deceptive conduct.  
5 Plaintiffs actually relied upon Defendants' misrepresentations and deception concerning the  
6 APAP Products.

7 138. Defendants engaged in the following unfair methods of competition or deceptive  
8 acts or practices, which are proscribed by law:

- 9 A. representing that goods or services have characteristics,  
10 ingredients, uses, benefits, or qualities they do not have; and  
11 B. advertising goods or services with the intent not to sell them as  
12 advertised; and  
13 C. engaging in fraudulent or deceptive conduct creating a likelihood  
14 of confusion or misunderstanding.

15 139. Plaintiffs were injured by the cumulative nature of Defendants's conduct. The  
16 cumulative effect, directed at patients, physicians, and consumers, was to create demand for and  
17 sell the APAP Products. Each aspect of Defendants' conduct combined to artificially create  
18 sales of the APAP Products, including to Plaintiff Mother who did, in fact, purchase the APAP  
19 Products.

20 140. Defendants had a statutory duty to refrain from unfair or deceptive acts or trade  
21 practices in the design, labeling, development, manufacture, promotion, and sale of the APAP  
22 Products.

23 141. Defendants' deceptive, unconscionable, or fraudulent representations and  
24 material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive  
25 acts and trade practices in violation of the federal and state consumer protection statutes listed  
26 below.

27 142. Defendants' actions, as complained of in this Complaint, constitute unfair  
28 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in

1 violation of the federal and state consumer protection statutes listed below.

2 143. Defendants has engaged in unfair competition, or unfair or deceptive acts or  
3 trade practices, or has made false representations under the following statutes:

- 4 • 15 U.S.C. §§ 2301–12 (1982);
- 5 • Cal. Bus. & Prof. Code § 17200, et seq.;
- 6 • Cal. Civ. Code § 1750 et seq.

7 144. To protect consumers against unfair, deceptive, fraudulent, and unconscionable  
8 trade and business practices, and false advertising, Defendants, as the supplier, manufacturer,  
9 advertiser, and seller, is subject to liability under the above legislation enacted against unfair,  
10 deceptive, fraudulent, and unconscionable consumer sales practices. The California Unfair  
11 Competition Law (“UCL”) prohibits “any unlawful, unfair, or fraudulent business act or  
12 practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by”  
13 Section 17500 of the California Business and Professions Code. Section 17500, in trun,  
14 prohibits any untrue or misleading statements made in connection with the sale of goods. The  
15 Consumers Legal Remedies Act (“CLRA”) defines as statutorily unlawful certain unfair  
16 methods of competition and unfair or deceptive practices. Cal. Civ. Code § 1750 et seq.

17 145. By knowingly and falsely representing that the APAP Products were fit to be  
18 used for the purposes for which they were intended—when in fact they were defective and  
19 dangerous when used during pregnancy—and by other acts alleged, Defendants violated the  
20 above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and  
21 unconscionable trade and business practices, and false advertising.

22 146. Defendants’ actions and omissions are uncured or incurable, deceptive acts under  
23 the above legislation.

24 147. Defendants had actual knowledge of the defective and dangerous conditions of  
25 the APAP products but failed to take any action to cure such defective and dangerous  
26 conditions.

27 148. Plaintiff Mother relied upon Defendants’ misrepresentations and omissions in  
28 determining which APAP Products (if any) to ingest.

149. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to consumers constituted unfair and deceptive acts and practices.

150. By reason of the unlawful acts in which Defendants engaged, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

151. As a direct and proximate result of Defendants' violations of the above-listed legislation, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages, including restitution, in an amount to be proven at trial and civil penalties as permitted by law.

**COUNT VI: NEGLIGENT MISREPRESENTATION**

152. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

153. Defendants had a duty to accurately and truthfully represent to consumers, including to Plaintiff Mother and to the public, that the APAP Products had not been adequately tested and found to be a safe and effective treatment for pregnant women. Defendants breached that duty as their representations of the safety of the APAP Products were false. Defendants intended for consumers like Plaintiff Mother to rely upon that representation, Plaintiff Mother did justifiably rely on Defendants' misrepresentations concerning the APAP Products' high risk of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

154. Defendants failed to exercise ordinary care in the representations concerning the APAP Products while Defendants were involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the APAP Products' high risk of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

155. Defendants also breached their duty in representing to Plaintiff Mother that the APAP Products had no serious side effects when ingested during pregnancy. Defendants intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff Mother did justifiably rely upon that representation.

157. As a direct and proximate result of Defendants's negligent misrepresentation, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

16 PUNITIVE DAMAGES

159. Defendants have acted with malice through despicable conduct that exhibits a willful and conscious disregard for the rights and safety of others, including Plaintiffs, and has acted with oppression in subjecting Plaintiffs to cruel and unjust hardship in conscious disregard of their rights. Further, Defendants have intentionally misrepresented or concealed material facts known to it with the intention of causing injury or otherwise depriving Plaintiffs of their property or legal rights.

160. Defendants failed to adequately test and study the APAP Products to determine  
and ensure that the APAP Products were safe and effective for use during pregnancy before  
releasing them for sale for human consumption.

28 161. Further, Defendants continued to manufacture and sell the APAP Products and

1 marketed them for use during pregnancy, even after obtaining knowledge and information that  
2 the APAP Products were defective and unreasonably unsafe because they, among other things,  
3 did not include adequate warnings.

4 162. Defendants was aware of the probable consequences of the dangerous and  
5 defective product, including the risk of neurodevelopmental disorders in children, such as ASD  
6 and ADHD, when they suffered prenatal exposure.

7 163. At all material times, Defendants knew or should have known that the APAP  
8 Products were inherently dangerous with respect to the following: the risk of  
9 neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered  
10 prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to  
11 cure the conditions proximately related to the use of the APAP Products, as well as the other  
12 permanent and lasting severe personal injuries.

13 164. Defendants knowingly withheld material information from consumers and the  
14 public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products  
15 during pregnancy, which deprived Plaintiff Mother of vitally necessary information with which  
16 to make a fully informed decision about whether to use the APAP Products while pregnant.

17 165. At all material times, Defendants also knew and recklessly and/or intentionally  
18 disregarded the fact that the APAP Products, when used during pregnancy, can cause  
19 debilitating and life-altering side effects with greater frequency than safer alternative methods,  
20 products, and/or treatments. But Defendants recklessly failed to advise the medical community  
21 and the general public, including Plaintiff Mother, of that fact.

22 166. At all material times, Defendants intentionally misstated and misrepresented  
23 data; and Defendants continue to misrepresent data so as to minimize the perceived risk of  
24 injuries and the rate of complications caused by or associated with the APAP Products.

25 167. Notwithstanding the foregoing and the growing body of knowledge and  
26 information regarding the true and defective nature of the APAP Products, with their increased  
27 risk of side effects and serious complications, Defendants continue to aggressively market the  
28



1 APAP Products to consumers, including the pregnant community at large, without disclosing  
2 the true risk of the complications and side effects.

3 168. When Plaintiff Mother consumed the APAP Products and since then, Defendants  
4 have known the APAP Products were defective and unreasonably dangerous without an  
5 adequate warning. But Defendants continued to manufacture, produce, assemble, market,  
6 distribute, and sell the APAP Products to the pregnant community so as to maximize sales and  
7 profits at the expense of the health and safety of expecting mothers in a conscious, reckless,  
8 and/or intentional disregard of the likely and foreseeable harm caused by the APAP Products to  
9 members of the public, including Plaintiffs.

10 169. At all material times, Defendants has concealed and/or failed to disclose to the  
11 public the serious risks and the potential complications associated with the APAP Products, so  
12 as to ensure continued and increased sales and profits and to the detriment of the public,  
13 including Plaintiffs.

14 170. Defendants' acts and omissions are of such character and nature so as to entitle  
15 Plaintiffs to an award of punitive damages in accordance with applicable statutory and common  
16 law. Defendants' conduct shows malice, oppression, or fraud, or that entire want of care,  
17 raising the presumption of conscious indifference to consequences of that conduct, thereby  
18 justifying an award of punitive damages.

19 WHEREFORE, Plaintiffs demand judgment against Defendants individually, and jointly  
20 and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced  
21 compensatory damages, together with interest, costs of suit, attorneys' fees, and such further  
22 relief as the Court deems equitable and just.

23 **PRAYER FOR RELIEF**

24 Plaintiffs demand judgment against Defendants, individually, and jointly and severally,  
25 and prays for the following relief in accordance with applicable law and equity:

- 26 i. Compensatory damages to Plaintiffs for past, present, and future  
27 damages, including pain and suffering for severe and permanent personal  
28 injuries sustained by Plaintiffs, permanent impairment, mental pain and

suffering, loss of enjoyment of life, health and medical care costs,  
economic damages, together with interest and costs as provided by law;  
and

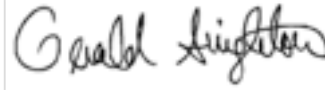
- ii. Restitution and disgorgement of Defendants's profits; and
- iii. Punitive or enhanced compensatory damages; and
- iv. Reasonable attorneys' fees as provided by law; and
- v. Past and future costs of all proceedings; and
- vi. All ascertainable economic damages; and
- vii. Prejudgment interest on all damages as allowed by law; and
- viii. Such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demands a trial by jury on all issues so triable.

Dated: August 26, 2022

Respectfully submitted,



Gerald Singleton  
California State Bar No. 208783  
[gsingleton@singletonschreiber.com](mailto:gsingleton@singletonschreiber.com)  
Singleton Schreiber, LLP  
2945 Townsgate Rd.  
Westlake Village, Suite 200  
Thousand Oaks, CA 91361  
Direct: (805) 256-1116

Mikal C. Watts (Pro Hac Forthcoming)  
Texas State Bar No. 20981820  
[mcwatts@wattsguerra.com](mailto:mcwatts@wattsguerra.com)  
Alicia D. O'Neill (Pro Hac Forthcoming)  
Texas State Bar No. 24040801  
[aoneill@wattsguerra.com](mailto:aoneill@wattsguerra.com)  
Watts Guerra LLC  
5726 W. Hausman Dr., Suite 119  
San Antonio, Texas 78249  
Direct: (210) 447-0500

*ATTORNEYS FOR PLAINTIFFS*